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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,198	03/31/2006	Nardino Righi	2504-1163	5636
466 YOUNG & TH	7590 09/17/2007 IOMPSON		EXAM	INER
745 SOUTH 23RD STREET			CAMPBELL, VICTORIA P	
2ND FLOOR ARLINGTON	, VA 22202		ART UNIT	PAPER NUMBER
			3709	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)			
	10/535,198	RIGHI ET AL.			
Office Action Summary	Examiner	Art Unit			
. 6.	Victoria P. Campbell	3709			
The MAILING DATE of this communication ap Period for Reply	ppears on the cover sheet with	the correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING E  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICA .136(a). In no event, however, may a reply d will apply and will expire SIX (6) MONTHS te, cause the application to become ABAN	TION.  be timely filed  from the mailing date of this communication.  DONED (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on 31 M	March 2006.				
3) Since this application is in condition for allows	ance except for formal matters	s, prosecution as to the merits is			
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 1	1, 453 O.G. 213.			
Disposition of Claims					
4)⊠ Claim(s) 1-18 is/are pending in the application	n.				
4a) Of the above claim(s) is/are withdra	awn from consideration.				
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-18</u> is/are rejected.					
7)⊠ Claim(s) <u>1-18</u> is/are objected to.					
8) Claim(s) are subject to restriction and/o	or election requirement.	·			
Application Papers					
9)⊠ The specification is objected to by the Examina	er.	•			
10)⊠ The drawing(s) filed on 18 May 2005 is/are: a	ı)  accepted or b)  objected	d to by the Examiner.			
Applicant may not request that any objection to the	e drawing(s) be held in abeyance	See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correct	ction is required if the drawing(s)	is objected to. See 37 CFR 1.121(d).			
11)☐ The oath or declaration is objected to by the E	xaminer. Note the attached O	ffice Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	•	19(a)-(d) or (f).			
<ul><li>1. Certified copies of the priority documen</li><li>2. Certified copies of the priority documen</li></ul>		ligation No			
<ul><li>2. Certified copies of the priority documen</li><li>3. Copies of the certified copies of the priority</li></ul>	• •				
application from the International Burea		Leived III triis National Stage			
* See the attached detailed Office action for a list	, , , ,	ceived.			
••					
Attachment(s)					
1) Notice of References Cited (PTO-892)		mary (PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/18/05.		ail Date mal Patent Application			

Art Unit: 3709

#### **DETAILED ACTION**

This is the initial Office Action based on the 10/535198, filed on March 31, 2006, which is a national stage entry under 35 USC § 371 of the PCT application IT02/00730 filed November 18, 2002. Claims 1-18 as amended and submitted May 18, 2005 are currently pending and considered below.

### Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: #54 in Figs. 1 and 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### Specification

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

# Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (I) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).
- 3. The disclosure is objected to because of the following informalities:

The specification lacks the proper headings as indicated above.

Page 3, lines 1 and 2 reference claim numbers, which are prohibited from use in the language of the disclosure.

Art Unit: 3709

Page 3, line 27 reads "support for a injection needle" but should read "support for an injection needle".

Page 3, lines 29-30 reads "can slide over the spring abutment member and the syringe body" which should be rewritten to include commas to read "can slide over the spring, abutment member, and syringe body".

Page 6, lines 35-36 reads "mounted on or built-in in a cylindrical" but should read "mounted on or built-in to a cylindrical".

Part 115 is referred to in the specification as both the head (page 6, line 29) and the tang (page 7, line 2). One consistent form of labeling should be used.

On page 9, line 32, the spring is "designed to be housed in the front part 52 of the sleeve body" but the front part is referenced as #51 in all other mentions in the application.

Appropriate correction is required.

## Claim Objections

4. Claim 1 is objected to because of the following informality: final bullet point lists "a abutment member". This is improper grammar. The phrase should read "an abutment member".

Claim 3 is objected to because of the following informalities: second line of claim reads "characterised in that in during operation" which is improper grammar. The claim should read "characterised in that during operation". Additionally, the final bullet point reads "to release said locking means (56)" which is an improper reference according to

the disclosure. The examiner has examined the claim with the assumption that the applicant intended the claim to read "to release said locking means (66)".

Claim 4 is objected to because of the following informality: uses the word "e" which is not a word in the English language. The word should be changed to "and".

Claim 9 is objected to because of the following informality: the claim reads "protruding radially outward form the rear" and should be corrected to read "protruding radially outward from the rear".

Claim 12 is objected to because of the following informalities: there is a period before the first bullet point, which should be removed; the fourth bullet point reads "said abutment member (7)" which is inconsistent numbering, the examiner has examined the claim with the assumption that applicant intended the claim to read "said abutment member (8)"; the third line from the end contains the phrase "so as allow axial movement" which should read "so as to allow axial movement".

Claim 15 is objected to because of the following informality: line 7 of the claim reads "said pairs of front tongues". The phrase should read "said pair of front tongues".

Claims 2-11 and 13-18 are objected to because of the following informalities: the word "characterised" is not the American English spelling of the word "characterized".

Appropriate correction is required.

## Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation "said locking means" in the second line of the amended claim. There is insufficient antecedent basis for this limitation in the claim. Claim 9 also recites the limitation "said flexible rear tongues" in lines 5-6 of the amended claims. There is insufficient antecedent basis for this limitation in the claim. Claim 10 recites the limitation "said circular operating crown" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the contrast element" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. The examiner takes note of the figure number assigned to "the contrast element" as the same one used for the "abutment member" as has treated the limitation as such during examination.

### Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

With respect to claim 1, Petrussa teaches

8. Claims 1-6 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,376,080 issued December 27, 1994 to Petrussa.

<sup>(</sup>b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a guard mechanism attachable to a syringe to make it into a disposable automatic safety syringe, said syringe comprising: a syringe body (Fig. 1, #14) hollow on the inside and open at the front and rear, a plunger (Col. 3, lines 57-58, notes a normal seal-engagement packing) sliding inside the syringe body with an injection stroke extending from a retracted syringe-filling position to a forward syringe-emptying position, said plunger being provided at the rear with a shaft (Fig. 1, #15) that can be operated manually and brought out of the syringe body by means of the rear end (Fig. 1, not labeled) thereof, and an injection needle (Fig. 1, #11) incorporated into a needle-carrier (Fig. 1, #16) engageable in the head of the syringe body (Fig. 1, not labeled), wherein said guard mechanism is arranged and adapted to be pre-assembled and comprises: a sleeve (Fig.1, #20) that can be slidably mounted on said syringe body, a spring (Fig. 1, #12) housed in said sleeve, and a abutment member (Fig. 1, #18) for said spring, also housed in said sleeve and able to be made integral with the front part of said syringe body.

Regarding claim 2, Petrussa teaches

a mechanism according to claim 1, characterised in that in said pre-assembled condition, said abutment member (Fig. 1, #18) for said spring (Fig. 1, #12) is retained by locking means (Fig. 1, #24) in the form of flexible tongues protruding inward from said sleeve (Fig. 1, #20).

With regards to claim 3, Petrussa teaches

a mechanism according to claim 1, characterised in that in during operation said sleeve (Fig. 1, #20) is slidably mounted on said syringe body (Col. 3, lines 61-66), to pass from a retracted position of use of the syringe, to a forward position of safety, wherein it covers said needle (Col. 2, lines 40-51), and said spring is disposed under compression in the front part of said sleeve, between said sleeve and said abutment member made integral with said syringe body (Fig. 1, spring [#12] is compressed between the front of the sleeve [#27] and the abutment ring [#18]), to urge the axial movement of the sleeve with respect to the syringe body. the mechanism further comprising: locking means disposed in the rear part of the sleeve (Fig. 4, #24) and in the rear part of the syringe body (Fig. 4, #25) in reciprocal engagement, to keep the sleeve locked in the retracted position of use against the action of said spring, and operating means disposed in said shaft (Fig. 4, #25) to release said locking means, when the plunger reaches the end of the injection stroke, so as to allow the axial movement of the sleeve into the safety position, thanks to the action of said spring.

With regards to claim 4, Petrussa shows the following

a mechanism according to claim 1, characterised in that said abutment member comprises: a cylindrical or frusto-conical body (Fig. 5a, #18), hollow on the inside to be applied to the front part of the syringe body, e a cylindrical or frusto-conical tang (Fig. 5a, unlabeled, but pictured as part of the retention element [#35]) with a smaller diameter than the body and protruding forward therefrom so as to give rise to a shoulder (Fig. 5a, unlabeled).

With regards to claim 5, Petrussa teaches the following

a mechanism according to claim 4, characterised in that said spring is a spiral spring (Fig. 6b, #12) disposed in the front part of the sleeve (Fig. 1, spring #12 is shown in compressed conformation), around the tang (Fig. 1, #35) of the abutment member, with one end of the spring abutting against a collar (Fig. 1, #27) protruding inward in the front edge of the front part of the sleeve and the other end of the spring abutting against the shoulder (Fig. 1, unlabeled) of the abutment member.

With regards to claim 6, Petrussa teaches

a mechanism according to claim 1, characterised in that formed in said sleeve are locking means cooperating with said abutment member to lock the sleeve when it is in its forward position of safety (Col. 4, lines 3-5, 9-13, and 18-22. Examiner notes that preventing extraction of the needle support from the outer protective container is the action performed by locking the sleeve in place).

Regarding claim 9, Petrussa teaches the following

a mechanism according to claim 1 characterised in that said locking means for locking the sleeve in the retracted position of use comprise a collar (Fig. 1, #25) protruding radially outward form the rear edge of the syringe body (Fig. 1, #14) able to abut against said flexible rear tongues (Fig. 1, #24) formed in the rear part of the sleeve (5), said flexible tongues ending in respective abutment surfaces (Fig. 1, not labeled) able to abut against said collar to retain the syringe body (see Fig. 4 for more detailed drawing of locking means).

Art Unit: 3709

With regards to claim 10, Petrussa teaches

a mechanism according to claim 9, characterised in that said flexible tongues (Fig. 4, #24) are inclined slightly inward to cooperate with said circular operating crown (Fig. 4, #26), when the plunger is at the end of the injection stroke.

With respect to claim 11, Petrussa teaches the following

a mechanism according to claim 1, characterised in that said sleeve has outwardly protruding gripping means, to give rise to a resting surface for the user's fingers (Fig. 1, not labeled. The outer flange of the sleeve that contains the teeth [#24] is usable as a gripping means for the user's fingers).

With respect to claim 12, Petrussa teaches

a disposable automatic safety syringe comprising: a syringe body (Fig. 1, #14) hollow on the inside and open at the front and rear, a plunger (Col. 3, lines 57-58, notes a normal seal-engagement packing) sliding in the syringe body with an injection stroke extending from a retracted syringe-filling position to a forward syringe-emptying position, said plunger being provided at the rear with a shaft (Fig. 1, #15) that can be operated manually and brought out of the syringe body by means of the rear end (Fig. 1, not labeled) thereof, an injection needle (Fig. 1, #11) supported by a needle-carrier (Fig. 1, #16) engageable to the front end (Fig. 1, #27) of the syringe body, a sleeve (Fig. 1, #20) slidably mounted over said syringe body, to pass from a retracted position of use of the syringe wherein the needle protrudes forward therefrom, to a forward position of safety, wherein it covers said needle, an abutment member (Fig. 1, #18) able to be made integral

with the front part of the syringe body, spring means (Fig. 1, #12) disposed under compression in the front part of said sleeve, between said sleeve and said abutment member to urge the axial movement of the sleeve with respect to the syringe body, locking means (Fig. 1, #24, #25) provided in the rear part of the sleeve and in the rear part of the syringe body, in reciprocal engagement, to keep the sleeve locked in the retracted position of use against the action of said spring means, and operating means (Fig. 1, #26) disposed in said shaft to disengage said locking means, when the plunger reaches the end of the injection stroke, so as allow axial movement of the sleeve into the safety position, thanks to the action of said spring means.

With regards to claim 13, Petrussa teaches the following

a syringe according to claim 12, characterised in that said abutment member comprises: a cylindrical or frusto-conical body (Fig. 5a, #18), hollow on the inside to be applied to the front part of the syringe body, and a cylindrical or frusto-conical tang (Fig. 5a, unlabeled, but pictured as part of the retention element) with a smaller diameter than that of the body and protruding forward therefrom so as to give rise to a shoulder (Fig. 5a, unlabeled).

Regarding claim 14, Petrussa teaches

a syringe according to claim 13, characterised in that said spring means comprise a spiral spring (Fig. 6b, #12) disposed inside the front part of the sleeve (Fig. 1, spring #12 is shown in compressed conformation), around the tang (Fig. 1, #35) of the abutment member, with one end of the spring abutting against a

Art Unit: 3709

collar (Fig. 1, #27) protruding inward in the front edge of the front part of the sleeve and the other end of the spring abutting against the shoulder of the abutment member (Fig. 1, unlabeled).

# Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 11. Claims 7, 8, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrussa (US 5,376,080) in view of Pre-Grant Publication US 2001/0037089 to Domici, Jr., and US Patent No. 4,737,144 to Choksi. Regarding claim 7, Petrussa teaches the limitations of the claim as set forth by the applicant in the above discussion of claim 6, with the exception of locking means for securing the sleeve in its forward position, comprising a pair of front tongues and a pair of back tongues, made by substantially u-shaped cuts in the sleeve, that abut against the abutment member on

both sides, preventing the sleeve from moving either direction after deployment. With respect to claim 7, Domici, Jr. teaches the following

a mechanism according to claim 6, characterised in that said locking means (Fig. 1, #16 and #20) to lock the sleeve (Fig 1, #40) in the forward position of safety comprise a pair of front tongues (Fig. 1, #16) opposed to a pair of rear tongues (Fig. 1, #20) formed in said sleeve, said pair of front tongues having rear abutment surfaces (Fig. 1, #24) able to abut against the shoulder (Fig. 2, #64) of the abutment member (Fig. 3, #60) and said pair of rear tongues having front abutment surfaces (Fig. 1, #28) to abut against the rear edge of the body (Fig. 2, #62) of the abutment member.

Domici, Jr. does not teach, however, that the tongues are formed on the sleeve of the device. Instead, in the device described by Domici, Jr., the tongues are on the syringe body itself. With respect to claim 7, Choksi teaches a single locking means (Fig. 1, #20) on the sleeve itself. Modifying the locking means of Domici, Jr. by moving them to the sleeve of the device from the syringe body as in Choksi is an obvious variant that yields predictable results. Petrussa, Domici, Jr., and Choksi all teach equivalent methods of locking a sliding needle guard in place in an extended position, shielding the needle of a syringe. Because Petrussa, Domici, Jr., and Choksi, all teach equivalent elements to perform the same task, modifying the locking mechanism of Petrussa with the combined teachings of Domici, Jr. and Choksi have been obvious to one of ordinary skill in the art.

With regards to claim 8, Choksi also teaches

Art Unit: 3709

a mechanism according to claim 7, characterised in that said pairs of opposed tongues of the sleeve (Fig. 1, #20) are flexible and are formed by means of substantially U-shaped opposed cuts (Fig. 1, not labeled) in the sleeve body, to be able to bend radially inward and outward with respect to the sleeve (Fig. 8).

With regards to claim 15, Petrussa teaches the claim limitations at described above regarding claim 12. Additionally, Petrussa teaches the following

a syringe according to claim 12 characterised in that in said sleeve there are formed locking means cooperating with said abutment member to lock the sleeve when it is in its forward position of safety (Col. 4, lines 3-5, 9-13, and 18-22. Examiner notes that preventing extraction of the needle support from the outer protective container is the action performed by locking the sleeve in place).

But Petrussa fails to teach locking means for securing the sleeve in its forward position, comprising a pair of front tongues and a pair of back tongues, made by substantially ushaped cuts in the sleeve, that abut against the abutment member on both sides, preventing the sleeve from moving either direction after deployment. Further regarding claim 15, Domici, Jr. teaches the following

said locking means (Fig. 1, #16 and #20) comprising a pair of front tongues (Fig. 1, #16) opposed to a pair of rear tongues (Fig. 1, #20) formed in said sleeve, said pairs of front tongues having rear abutment surfaces (Fig. 1, #24) able to abut against the shoulder (Fig. 2, #64) of the abutment member (Fig. 3, #60) and said

pair of rear tongues having front abutment surfaces (Fig. 1, #28) able to abut against the rear edge of the body (Fig. 2, #62) of the abutment member.

Domici, Jr. does not teach, however, that the tongues are formed on the sleeve of the device. Instead, in the device described by Domici, Jr., the tongues are on the syringe body itself. With respect to claim 15, Choksi teaches a single locking means (Fig. 1, #20) on the sleeve itself. Modifying the locking means of Domici, Jr. by moving them to the sleeve of the device from the syringe body as in Choksi is an obvious variant that yields predictable results. Petrussa, Domici, Jr., and Choksi all teach equivalent methods of locking a sliding needle guard in place in an extended position, shielding the needle of a syringe. Because Petrussa, Domici, Jr., and Choksi, all teach equivalent elements to perform the same task, modifying the locking mechanism of Petrussa with the combined teachings of Domici, Jr. and Choksi have been obvious to one of ordinary skill in the art.

Regarding Claim 16, Petrussa teaches the following

a syringe according to claim 15 characterised in that said locking means for locking the sleeve in the retracted position of use comprise a collar (Fig. 1, #25) protruding radially outward form the rear edge of the syringe body (Fig. 1, #14) and able to abut against the pair of flexible rear tongues (Fig. 1, #24) formed in the rear part of the sleeve. (See Fig. 4 for more detailed drawing of locking means).

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petrussa (US 5,376,080) in view of US Patent 7,118,552 to Shaw et al. Petrussa teaches all of the limitations of claim 17 as set forth by the applicant, with the exception of a removable safety tab to prevent the full injection stroke (see above notes on claim 12). With respect to claim 17, Shaw et al teach the following:

a syringe according to claim 12 characterised in that in the rear part of said shaft (Fig. 4, #450) of the plunger (Fig. 4, #450) there is provided a safety tab (Fig. 4, #470) removable by the user (Col. 12, line 54) and able to abut against the rear edge of the sleeve to prevent the plunger from reaching the end of the injection stroke (Col. 6, lines 11-16).

The plunger of Petrussa could be compressed fully at any time, releasing the shield at a time when the operator did not intend (i.e. before or during use). Shaw et al teach a safety tab attached to the plunger of a syringe to prevent full movement of the plunger because full movement of the plunger engages the retraction mechanism, as does full movement of the plunger in the present invention. Thus, it would have been obvious to one of ordinary skill in the art of syringes to add the removable safety tab of Shaw et al to the syringe of Petrussa in order to prevent the user from retracting the syringe into the sleeve before the operator was prepared for disposal.

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petrussa (US 5,376,080) in view of US Patent No. 6,419,658 B1 to Restelli et al. Petrussa teaches all of the limitations of claim 18 as set forth by the applicant with the exception

of the tang of the abutment member being shaped as a Luer cone (see above notes on claim 13). With respect to claim 18, Restelli et al teach the following:

a syringe according to claim 13 characterised in that said tang (Fig. 4, #18) of the contrast element (Fig. 4) is shaped on the inside as a Luer cone to support the needle-carrier (Fig. 4, #22).

Examiner notes that Luer fittings are commonly used for syringe connections and would make the syringe compatible with pre-existing needles. The widespread use of Luer fittings, including Luer cones, would have made their use in this particular invention obvious to one of ordinary skill in the art.

### Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 6,616,639 to Gagnieux et al also uses the U-shaped cut outs to create tongues on the shield as described by the applicant in claim 8. Additionally, US Patent Application Publication 2003/0050601 A1 to Righi et al also shows a removable tab as described by the applicant in claim 17.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victoria P. Campbell whose telephone number is 571-270-5035. The examiner can normally be reached on Monday-Thursday, 7:30-5, Alternate Fridays 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3709

Page 18

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**VPC** 

SUPERVISORY PATENT EXAMINER